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Date of Deposit: April 13, 2006

Selena Whitaker-Paquiet

Attorney Docket No. 20371.0004c4
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of **Barbara A. BREWITT**

Group Art Unit: 1647

Serial No.	:	10/001,367
Filed	:	October 30, 2001
For	:	**HOMEOPATHIC PREPARATIONS OF PURIFIED INSULIN-LIKE GROWTH FACTOR-1**
Examiner	:	Jegatheesan Seharaseyon, Ph.D.

APPEAL BRIEF

MAIL STOP: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant **Barbara A. BREWITT**, by and through her attorney, hereby submits this Appeal Brief.

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I. REAL PARTY IN INTEREST

Barbara A. Brewitt, and Biomed Comm, Inc., the exclusive licensee of the subject patent application, are the real parties in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1, 2, 9-11, 13-23, 29 and 30 are finally rejected and are being appealed. Claims 24-28 are allowed and are not at issue in this appeal. Claims 3-8, and 12 were canceled during prosecution and are not at issue in this appeal.

IV. STATUS OF AMENDMENTS

Applicant's amendment after final rejection was entered for purposes of appeal as indicated in the Advisory Action mailed October 4, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER BEING APPEALED

The final rejection of claims 1, 2, 9-11, 13-23, 29 and 30 is appealed. Claim 1 is independent and claims 2, 9-11, 13-23, 29 and 30 are dependent.

Independent claim 1 recites a preparation comprising a homeopathic potency of purified insulin-like growth factor-1 (IGF-1) suitable for oral administration, wherein the concentration of the purified IGF-1 is less than 1×10^{-6} molar, and wherein the homeopathic potency is formulated in a liquid or solid formulation. Support for claim 1 can be found, for example, on page 11, lines 5-8, and page 18, lines 10-11 of the specification as filed. Dependent claim 2 specifies additional components that may comprise the preparation. Support for claim 2 can be found, for example, on page 19, lines 17-20 of the specification as filed. Dependent claim 9 specifies that the homeopathic potency of IGF-1 is impregnated on a solid medium. Support for claim 9 can be found, for example, in the paragraph beginning on page 21, line 18 and ending on page 22, line 11 of the specification as filed. Dependent claim 10 specifies that the purified IGF-1 is at least 95% pure. Support for claim 10 can be found, for example, in the section beginning on page 18, line 27 and ending on page 19, line 1 of the specification as filed. Dependent claim 11 specifies that the purified IGF-1 is a recombinant human protein. Support for claim 11 can be found, for example, on page 19, lines 1-7 of the specification as filed. Dependent claim 13 specifies that the purified IGF-1 has a homeopathic potency selected from the group consisting of: 6X, 6C, 15X, 12C, 30C, 100C, 200C, and 1M (1000C). Support for claim 13 can be found, for example, on page 18, lines 14-16 of the specification as filed. Dependent claim 14 specifies that the preparation of claim 1 additionally comprises a homeopathic potency of a substance selected from the group consisting of: FGF, PDGF, interleukin-2, and a hepatocyte growth factor. Support for claim 14 can be found, for example, in the paragraph beginning on page 14, line 23, and ending on page 15, line 6 of the specification as filed.

Dependent claim 15 specifies that the preparation of claim 1 comprises a combination potency formulation having at least two homeopathic potencies. Dependent claim 16 specifies that the preparation of claim 1 comprises a combination potency formulation of 6X and 12C homeopathic potencies. Dependent claim 17 specifies that the preparation of claim 1 comprises a combination potency formulation of 6C, 100C, and 200C homeopathic potencies. Dependent claim 18 specifies that the preparation of claim 1 comprises a combination potency formulation

of 6C and 1M homeopathic potencies. Support for claims 15-18 can be found, for example, on page 19, lines 8-16 of the specification as filed. Dependent claim 19 specifies that the preparation of claim 1 additionally comprises one or more traditional homeopathics selected from the group consisting of: arsenicum, pulseatilla, aconite, hypericum, and metabolic sarcodes. Support for claim 19 can be found, for example, on page 19, lines 22-24 of the specification as filed. Dependent claim 20 specifies that the preparation of claim 1 additionally comprises a homeopathic potency of purified growth hormone. Support for claim 20 can be found, for example, on page 9, lines 21-22 of the specification as filed.

Dependent claim 21 specifies that homeopathic potency of the IGF-1 of claim 1 is 30C. Dependent claim 22 specifies that homeopathic potency of the IGF-1 of claim 1 is 1M. Dependent claim 23 specifies that homeopathic potency of the IGF-1 of claim 1 is 6C. Support for claims 21-23 can be found, for example, on page 18, lines 14-16 of the specification as filed. Dependent claim 29 specifies the liquid formulation of the preparation recited in claim 1 is an aqueous solution. Support for claim 29 can be found, for example, on page 21, lines 4-10 of the specification as filed. Dependent claim 30 specifies the solid medium of the preparation recited in claim 9 is a tablet. Support for claim 30 can be found, for example, in the paragraph beginning on page 21, line 18 and ending on page 22, line 11 of the specification as filed.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejection of claims 1, 9, 10, 14 and 30 under 35 U.S.C. § 102(b) as being anticipated by *Antoniades et al.* (U.S. Patent No. 5,035,887) is appealed. The rejection of claims 13, 15-18 and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over *Antoniades et al.*, in view of *Vithoulkas et al.* (1981) is appealed. The rejection of claims 2, 3, 11, 20 and 29 under 35 USC § 103(a) as being unpatentable over *Antoniades et al.* in view of *Clark et al.* (U.S. Patent No. 5,597,797) is appealed. The rejection of claim 19 under 35 USC 103(a) as being unpatentable over *Antoniades et al.* in view of *Whitson-Fischman et al.* (U.S. Patent No. 5,162,037) is appealed.

VII. ARGUMENT

Claim Rejections – 35 U.S.C. §102(b)

Claims 1, 9, 10, 14 and 30 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by *Antoniades et al.* (U.S. Patent No. 5,035,887). Claims 10 and 14 rise or fall with claim 1; the patentability of claims 9 and 30 is argued independently from that of claims 1, 10, and 14.

A claim is anticipated under 35 U.S.C. § 102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628,631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377 (Fed. Cir. 2005).

Antoniades et al. is directed to healing an external wound in a mammal, *e.g.*, a human patient, by applying to the wound an effective amount of a composition that includes a combination of purified PDGF and purified IL-1, or purified IGF-1 and purified IL-1. *See*, Col. 2, lines 10-14. The compositions of *Antoniades et al.* are prepared using a pharmaceutically acceptable carrier substance, e.g. commercially available inert gels, or membranes, or liquids. *See*, Col. 2, lines 26-29. The disclosure and teachings of *Antoniades et al.* are directed, exclusively, to the treatment of external wounds, *e.g.* bed sores and burns, with the combination compositions.

The Examiner states that applicant's Claim 1, reciting a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration, is encompassed by *Antoniades et al.* Specifically, the Examiner states that the pharmaceutically acceptable carriers described in *Antoniades et al.* can also be used for oral administration. In addition, the Examiner states that *Antoniades et al.* encompasses homeopathic potency by using 500ng - 1μg of IGF- and that *Antoniades et al.* teach the inclusion of IGF-1 in a gel which could also be used in a tablet for oral administration.

It is true that the compositions of *Antoniades et al.* comprise IGF-1 in combination with IL-1 at "low" concentrations. Applicant's independent claim 1 specifies a preparation having a concentration of less than 1×10^{-6} molar insulin-like growth factor-1, but **it also requires that**

the preparation comprise a *homeopathic potency*. Homeopathic potencies, as evidenced by applicant's specification and the materials of record in the prosecution of this application relating to homeopathy and homeopathic preparations, are made using specialized and standardized techniques involving both serial dilutions and serial succussions. It is the preparatory process, and not merely the highly dilute concentration, that renders a preparation a ***homeopathic potency***. Preparation of homeopathic potencies is described, for example, in VITHOULKAS, George; "The Science of Homeopathy," pp. 157-167 (1980 Grove Press, New York); LEROY, Debra; "Potencies," www.medicinegarden.com/Homeopathy/Potencies (1998), printed 10/16/2000; BELLAVITE, Paolo M.D., et al.; "Homeopathy – A Frontier in Medical Science," pp. 11-12 (1995 North Atlantic Books, California). These references are listed on the accompanying Evidence Appendix and copies of the references are provided.

There is no teaching or suggestion whatsoever in *Antoniades et al.* that the compositions are prepared homeopathically to produce homeopathic potencies. There is no description, either expressly or inherently, of homeopathic potencies, or of serial dilutions and serial succussions. No homeopathic nomenclature is used. It is submitted, therefore, that *Antoniades et al.* does ***not*** anticipate applicant's claims 1, 10 and 14, which all require, *inter alia*, a preparation comprising a ***homeopathic potency*** of purified IGF-1.

There is, additionally, no teaching or suggestion in *Antoniades et al.* of an IGF-1 preparation suitable for oral administration, particularly where the preparation is formulated in a liquid or solid formulation. The disclosure of *Antoniades et al.* is directed *exclusively* to the treatment of external wounds. *See, e.g.*, Abstract, line 1, Col. 2, lines 10-11, Col. 2, lines 62-64, and Col. 3, line 15. The Examiner argues that the pharmaceutically acceptable carriers referred to in *Antoniades et al.,* such as liquids and gels, can also be used for oral administration. The Examiner's proposition that because one *could* ingest the "pharmaceutically acceptable" and/or "inert" gels or carriers formulated for topical use in wound healing applications by *Antoniades et al.* orally, the applicant's claims are thereby anticipated, cannot be sustained. If one *could* ingest a gel of *Antoniades et al.* intended for topical application to external wounds such as sores and burns and, because the gel is inert, it would do no harm, this happenstance does *not* constitute an express or inherent description of a composition suitable for oral administration that would anticipate applicant's claims 1, 10 and 14 in the manner required by 35 U.S.C. 102(b).

Applicant's claim 9 specifies that the homeopathic potency of IGF-1 is impregnated on a solid medium. As pointed out above, *Antoniades et al.* do not disclose or suggest homeopathic potencies of IGF-1. Moreover, applicant's representative can find no reference in *Antoniades et al.* to a homeopathic potency of IGF-1 *impregnated on a solid medium.* The Examiner argues, in the final rejection mailed June 13, 2005, that "*Antoniades et al.* also teach the inclusion of IGF-1 in a gel (column 5, lines 5-15) meeting the limitation of claim 9." *See*, Final Rejection mailed June 13, 2005, p. 3.

Antoniades et al. disclose the use of commercially available inert gels for formulation of their external wound healing compositions. The combination or formulation of the active composition with the inert gel is not described in detail by *Antoniades et al.* With reference to the data demonstrating wound healing provided in the specification, *Antoniades et al.* state that the wounds were treated directly with a single application of (specified) growth factors "suspended in biocompatible gel." *See*, Col. 5, lines 7-15. Absent any description in the specification of what *Antoniades et al.* mean by a "gel," we must look to find the ordinary meaning of the word, to determine how one of ordinary skill in the art would interpret that terminology. The term "gel" is defined, in Webster's New World Dictionary, Second College Edition, Simon and Schuster, 1982, as "a jellylike substance formed by the coagulation of a colloidal solution into a solid phase." Applicant submits that the inclusion of IGF-1 in a gel does not anticipate, either expressly or inherently, a homeopathic potency of IGF-1 impregnated on a solid medium.

Applicant's claim 30 depends from claim 9 and further specifies that the solid medium is a tablet. As pointed out above, *Antoniades et al.* do not disclose or suggest homeopathic potencies of IGF-1. Moreover, applicant's representative can find no reference in *Antoniades et al.* to a homeopathic potency of IGF-1 *impregnated on a solid tablet.* The Examiner argues, in the final rejection mailed June 13, 2005, that an inert gel could also be a tablet for oral administration, meeting the limitation of claim 30. Applicant submits, for the reasons stated above, that the inclusion of IGF-1 in a gel does *not* anticipate, either expressly or inherently, a homeopathic potency of IGF-1 impregnated on a solid tablet.

The teachings of *Antoniades et al.* do *not* describe, expressly or inherently, homeopathic potencies and they do not describe, expressly or inherently, oral formulations. Independent claim 1 and dependent claims 9, 10, 14 and 30, specify a preparation comprising a ***homeopathic potency*** of purified insulin-like growth factor-1 suitable for *oral administration*,that is *formulated in a liquid or solid formulation.* It is submitted that applicant's claims are ***not*** anticipated by *Antoniades et al*, and that the rejection of the claims under 35 U.S.C. §102(b) must be withdrawn.

Claim Rejections – 35 U.S.C. §103(a) - Antoniades et al.*, in view of *Vithoulkas et al.

Claims 13, 15-18, and 21-23 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Vithoulkas et al.* The patentability of claims 13 and 21-23 is argued separately from the patentability of claims 15-18.

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005); *see* 35 U.S.C. § 103. In determining whether a combination of elements is non-obvious, it must be assessed whether, in fact, an artisan of ordinary skill in the art at the time of invention, with no knowledge of the claimed invention, would have some motivation to combine the teachings of one reference with the teachings of another reference. *Id.*

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP 2142 citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 13 and 21-23 are dependent from claim 1 and recite preparations comprising specific homeopathic potencies of IGF-1, including potencies of 6X, 6C, 15X, 12C, 30C, 100C, 200C and 1M. The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above and incorporated with reference to this rejection. *Antoniades et al.* do not teach or suggest any homeopathic potencies, much less specific homeopathic potencies. *Vithoulkas et al.* describe standard protocols and nomenclatures for homeopathic potencies without reference to or suggestion of specific homeopathic compositions. The Examiner states, in the final rejection, that *Vithoulkas et al.* teaches various potencies used in homeopathy for therapeutic purposes. Applicant finds no motivation, in either of the references or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings, in the manner suggested by the Examiner. This rejection cannot be sustained.

Claims 15-18 are dependent from claim 1 and recite preparations comprising at least two homeopathic potencies of IGF-1, including formulations comprising 6X and 12C homeopathic potencies (Claim 16), 6C, 100C and 200C homeopathic potencies (Claim 17) and 6C and 1M homeopathic potencies (Claim 18). The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above and incorporated with reference to this rejection. *Antoniades et al.* do not teach or suggest any preparations comprising homeopathic potencies, much less specific homeopathic potencies. *Vithoulkas et al.* describe standard protocols and nomenclatures for homeopathic potencies without reference to or suggestion of specific homeopathic compositions. The Examiner states, in the final rejection, that *Vithoulkas et al.* teaches various potencies used in homeopathy for therapeutic purposes. Applicant finds no motivation, in either of the references or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings, in the manner suggested by the Examiner. This rejection cannot be sustained.

Vithoulkas et al. does not overcome the deficiencies of *Antoniades et al.* with respect to applicant's claimed preparations. Applicant does not discern any teaching or suggestion in *Antoniades et al.* or *Vithoulkas et al.*, or any combination of those references, that would anticipate or render obvious applicant's claims 13, 15-18 and 21-23, nor does applicant discern

any motivation for combining the teachings of these references. Allowance of these claims is respectfully solicited.

Claim Rejections – 35 U.S.C. §103(a) - Antoniades et al.*, in view of *Clark et al.

Claims 2, 11, 20 and 29 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Clark et al.* (U.S. Patent No. 5,597,797). The patentability of each of claims 2, 11, 20 and 29 is argued separately.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above and incorporated with reference to this rejection. *Antoniades et al.* do not teach or suggest any preparations comprising homeopathic potencies. *Clark et al.* disclose methods for treating obesity by administering an effective amount of growth hormone (GH) in combination with an effective amount of IGF-1. GH administration is by continuous infusion (using, e.g., an osmotic pump) or by injections more frequent than once a day and may be administered in a form in which it is bonded to a polymer. Similar administrations of IGF-1 are described. The dose for each component is on the order of micrograms to milligrams/kg body weight/day. These dosages are ***not*** at the concentrations set out in applicant's claims, nor is there any indication that the dosages are prepared homeopathically as would be required to produce homeopathic potencies. Fundamental claim requirements are not described by either *Antoniades et al.* or *Clark et al.*, or by any combination of their teachings. Furthermore, Applicant finds no motivation, in either of the references or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teaching, in the manner suggested by the Examiner. This rejection cannot be sustained.

Applicant's Claim 2 specifies a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration, and additionally comprising at least one component selected from the group consisting of: a vitamin, a mineral, an amino acid, carnitine, CoQ10, vitamin K, vitamin E, Ginko Biloba, Phosphadityl Serine, an Omega 3 oil, flax seed, fish oil, polyamines, alpha hydroxy, glycolytic acid, and DHA. The Examiner alleges that *Clark et al.* teaches preparations containing "various combinations including GH and amino acids." Even if this were true, it would provide a teaching of only one of the claim elements. There is

still no combination of the references relied upon by the Examiner that provides, for example, any teaching of a preparation comprising a homeopathic potency of IGF-1. Furthermore, there is no rationale or motivation for combining the references. For these reasons, this rejection cannot be sustained. Applicant's claim 11 specifies a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration wherein the purified IGF-1 is a recombinant human protein. *Clark et al.* disclose the use of recombinant human proteins, including IGF-1. However, there is still no combination of the references relied upon by the Examiner that provides, for example, any teaching of a preparation comprising a homeopathic potency of IGF-1. Moreover, there is no rationale or motivation for combining the references. For these reasons, this rejection cannot be sustained.

Applicant's claim 20 specifies a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration, and further comprising a homeopathic potency of purified growth hormone. *Clark et al.* disclose the use of growth hormone (GH) in combination with IGF-1 for treating or preventing obesity. Neither *Antoniades et al.* nor *Clark et al.* discloses, or suggests, the use of a ***homeopathic potency*** of either growth hormone or IGF-1. There is no combination of *Antoniades et al.* and *Clark et al.* that provides, for example, any teaching of a preparation comprising a homeopathic potency of IGF-1, particularly in combination with a homeopathic potency of growth hormone. Moreover, there is no rationale or motivation for combining the references as proposed by the Examiner. For these reasons, this rejection cannot be sustained.

Applicant's claim 29 specifies a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration, wherein the liquid form is an aqueous solution. As set out above, neither *Antoniades et al.* nor *Clark et al.* discloses, or suggests, the use of a ***homeopathic potency*** of either growth hormone or IGF-1. There is no combination of *Antoniades et al.* and *Clark et al.* that provides, for example, any teaching of a preparation comprising a homeopathic potency of IGF-1 in an aqueous solution. Moreover, there is no rationale or motivation for combining the references as proposed by the Examiner. For these reasons, this rejection cannot be sustained.

Claim Rejections – 35 U.S.C. §103(a) - Antoniades et al.*, in view of *Whitson-Fischman et al.

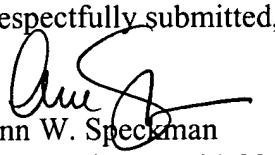
Claim 19 has been finally rejected under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Whitson-Fischman* (U.S. Patent No. 5,162,037). Claim 19 specifies a preparation comprising a homeopathic potency of IGF-1 in combination with one or more traditional homeopathics selected from the group consisting of: arsenicum, pulseatilk, aconite, hypericum and metabolic sarcodes. The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above and incorporated with reference to this rejection. *Whitson-Fischman* discloses magnetizing homeopathic mixtures of herbs, herbal extracts and other compounds and administering such homeopathic medicaments through selected acupuncture points. Various delivery forms of homeopathic preparations are described. Applicant does not perceive that *Whitson-Fischman* discloses or suggests the use of homeopathic potencies of purified IGF-1 or other purified growth factors. *Whitson-Fischman*, rather, discloses the use of more conventional herb-based homeopathic medicaments.

It is urged that *Whitson-Fischman* does not overcome the deficiencies of *Antoniades et al.* with respect to applicant's claim 19 and that no combination of the *Antoniades et al.* and *Whitson-Fischman* renders the preparations of claim 19 obvious in the manner required by 35 U.S.C. §103(a). Moreover, there is no rationale or motivation for combining the references as proposed by the Examiner. For these reasons, this rejection cannot be sustained.

Conclusion

Applicant submits that all of the pending claims are allowable and should be allowed. Allowance of all the pending claims on appeal is respectfully requested.

Respectfully submitted,



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Date: February 14, 2006

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20601

VIII. CLAIMS APPENDIX

This listing of claims represents all the claims pending in the appeal.

Listing of Claims:

Claim 1 (previously presented): A preparation comprising a homeopathic potency of purified insulin-like growth factor-1 (IGF-1) suitable for oral administration, wherein the concentration of said purified insulin-like growth factor-1 is less than 1×10^{-6} molar, and wherein said homeopathic potency is formulated in a liquid or solid formulation.

Claim 2 (previously presented): A preparation as recited in claim 1 additionally comprising at least one component selected from the group consisting of: a vitamin, a mineral, an amino acid, carnitine, CoQ10, vitamin K, vitamin E, Ginko Biloba, Phosphadityl Serine, an Omega 3 oil, flax seed, fish oil, polyamines, alpha hydroxy, glycolytic acid, and DHA.

Claim 9 (previously presented): A preparation as recited in claim 1 wherein the homeopathic potency of IGF-1 is impregnated on a solid medium.

Claim 10 (previously presented): A preparation as recited in claim 1, wherein the purified insulin-like growth factor-1 is at least 95% pure.

Claim 11 (previously presented): A preparation as recited in claim 1, wherein the purified insulin-like growth factor-1 is a recombinant human protein.

Claim 13 (previously presented): A preparation as recited in claim 1 wherein the purified insulin-like growth factor-1 has a homeopathic potency selected from the group consisting of: 6X, 6C, 15X, 12C, 30C, 100C, 200C, and 1M (1000C).

Claim 14 (previously presented): A preparation as recited in claim 1, additionally comprising a homeopathic potency of a substance selected from the group consisting of: a fibroblast growth factor (FGF), a platelet-derived growth factor (PDGF), an interleukin-2, and a hepatocyte growth factor.

Claim 15 (previously presented): A preparation as recited in claim 1 comprising a combination potency formulation having at least two homeopathic potencies.

Claim 16 (previously presented): A preparation as recited in claim 15, wherein the combination potency formulation comprises 6X and 12C homeopathic potencies.

Claim 17 (previously presented): A preparation as recited in claim 15, wherein the combination potency formulation comprises 6C, 100C, and 200C homeopathic potencies.

Claim 18 (previously presented): A preparation as recited in claim 15, wherein the combination potency formulation comprises 6C and 1M homeopathic potencies.

Claim 19 (previously presented): A preparation as recited in claim 1, additionally comprising one or more traditional homeopathics selected from the group consisting of: arsenicum, pulseatilla, aconite, hypericum, and metabolic sarcodes.

Claim 20 (previously presented): A preparation as recited in claim 1, further comprising a homeopathic potency of purified growth hormone.

Claim 21 (previously presented): A preparation as recited in claim 1, wherein the homeopathic potency of IGF-1 is 30C.

Claim 22 (previously presented): A preparation as recited in claim 1, wherein the homeopathic potency of IGF-1 is 1M.

Claim 23 (previously presented): A preparation as recited in claim 1, wherein the homeopathic potency of IGF-1 is 6C.

Claim 29 (previously presented): A preparation as recited in claim 1, wherein the liquid form is an aqueous solution.

Claim 30 (previously presented): A preparation as recited in claim 9, wherein the solid medium is a tablet.

IX. EVIDENCE APPENDIX

1. VITHOULKAS, George; "The Science of Homeopathy," pp. 157-167 (1980 Grove Press, New York). Submitted in an Amendment and Reply received by the USPTO February 28, 2005.

2. LEROY, Debra; "Potencies," www.medicinegarden.com/Homeopathy/Potencies; printed 10/16/2000 (1998). Submitted in an Amendment and Reply received by the USPTO February 28, 2005.

3. BELLAVITE, Paolo M.D., et al.; "Homeopathy – A Frontier in Medical Science," pp. 11-12 (1995 North Atlantic Books, California). Submitted in an Amendment and Reply received by the USPTO February 28, 2005.

The Science of Homeopathy

by
GEORGE VITHOULKAS

With a Foreword by
WILLIAM A. TILLER

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Chapter 11

Preparation of Medicines

ANY THERAPEUTIC METHOD must master the technical aspects of the materials being used if there is ever to be any hope for achieving reproducible results. Standards of materials and methods must be carefully established and strictly followed. This is as true in homeopathy as it is in all other sciences.

Mostly, the burden of technical standardization has fallen on the shoulders of homeopathic pharmacists. Considering the smallness of the dose being administered to each patient, it is easy to imagine the problems facing these pharmacists in properly making a profit. Despite their difficulties, they have thus far done an admirable job in provdiing homeopaths the world over with excellent medicines of reliable standard. However, if these standards are to be maintained, every practitioner must take steps to support the pharmacists preparing and dispensing our precious remedies. It is not enough to simply gather remedies into our offices and blindly take for granted that the supply will always be there. On the contrary, we must make arrangements whereby the pharmacists are benefited by our prescriptions just as we and our patients are. If this is not done, the reliability, and eventually the availability, or remedies will disappear altogether; this can as surely bring about the death of homeopathy as can the opposition of governments of orthodox medical societies.

In considering technical standards for the actual production of homeopathic medicines, we must first put attention on the initial

carried out in the standard manner described below. If, however, the substance is not soluble in alcohol, a specific method of *trituration* is used to bring it to the millionth dilution in a form soluble in alcohol. This involves grinding the material with a specific amount of milk sugar in a mortar and pestle for a total of three hours. The method is highly specific and has not changed since Hahnemann's first description (see Annotated Bibliography).

As we know, such a first-level preparation enables the energetic potential of material substances to be liberated, but it also has purely chemical effects which are difficult to comprehend. Again Hahnemann describes this effect:

> *Not only, as shown elsewhere, do these medicinal substances thereby develop their powers in a prodigious degree, but they also change their physico-chemical demeanor in such a way, that if no one before could ever perceive in their crude form any solubility in alcohol or water, after this peculiar transmutation they become wholly soluble in water as well as in alcohol—a discovery invaluable to the healing art . . .*
>
> *What can I say of the pure metals and of their sulphurets, but that all of them, without any exception become by this treatment equally soluble in water and in alcohol, and every one of them develops the medicinal virtue peculiar to it in the purest, simplest manner and in an incredibly high degree?* [3]

Standard Preparation

Once the remedy has been prepared in a soluble form to the 6× potency the typical method of potentization described in Chapter 7 is used. One drop is diluted in a certain amount of solvent (either 9, 99, or 50,000 drops), and the resulting solution is shaken forcefully for a definite number of successions. One drop of this solution is then diluted and succussed similarly, and the process is continued indefinitely.

The dilution and succussion may be done either by hand or by machine. Nowadays, it is more efficient to use machines which can perform the process rapidly and tirelessly. Even with machines, however, a high potency remedy often takes as many as three months to make. A variety of machines have been devised to perform the succussions. The important point is that the number of succussions should be standardized; experiences shows that there should be between 40 and 100 succussions at each potency level. Also, the force of each succussion should be equivalent to

3. Hahnemann, *Chronic Diseases*, p. 145.

or greater than the force that a man's arm can deliver when striking the hand-held vial forcefully against a firm surface (such as a leather-bound book, as described by Hahnemann). Machines must be monitored carefully as to the number and force of succussions, so that no mechanical errors can enter into the standardization of the preparations.

Of course, the practice of some unscrupulous pharmacies to succuss only after every 5 or 10 dilutions must be deplored and rejected. In addition, the modern tendency to develop machines which apply kinetic energy in unconventional ways (i.e., by ultrasound, by shooting a jet of solvent into a swirling vat, etc.) must be rejected. In a purely physical sense, such deviations might be effective, but the vast body of homeopathic experience has thus far been built upon medicines prepared by the standard method described above; therefore, major alterations introduce serious uncertainties into interpretation of results. Any changes in technique must be tested experimentally very thoroughly over a long period of time to confirm their validity. Conscientious practitioners must take the responsibility to determine the specific methods used in preparing their remedies and only purchase medicines from those pharmacies maintaining the highest of classical standards.

At present, there are two equally *valid* methods of preparing dilution. The Hahnemannian method takes one drop of the previous potency diluted into alcohol, succusses, and then discards the glass vial after preparing each potency. The Korsakoff method pours out the solvent from the previous potency, leaving a drop on the walls of the vial (which has been determined to be a consistent size each time), and then adds the new solvent for the next potency; thus by the Korsakoff method the same vial is used for each potency. Of course, even in the Korsakoff method, it is desirable from time to time to set aside intermediate potencies for storage, so the total number of vials used for, say, a 200 potency might be 6 or 8, whereas by the Hahnemannian method 200 vials would be required.

The difference between Hahnemannian and Korsakoff preparations has sparked considerable controversy among homeopaths. The argument against the Korsakoff method is that it might result in a mixture of potencies from one level to another. To me, this argument doesn't make sense. After all, when the dilution is made and the vial succussed, the entire solution and vial have been raised to a new amplitude of vibration. How can any one portion

of the solution avoid undergoing the same change as all other portions? Therefore, there cannot be "contamination" from one potency to another.

This is not a merely academic distinction. It has tremendous practical importance to homeopathic pharmacists. To perform the Hahnemannian method, a very large number of vials must be used, and old vials can be re-used only by heating in an oven to very high temperatures. Such a procedure is very expensive, of course, and unnecessary. In order to help preserve our pharmacies, and their standards, the Korsakoff method is preferable.

Hahnemann's original potencies were made in alcohol, but this again places a great burden upon pharmacies producing high potency remedies. Since alcohol cannot be re-used, tremendous volumes of alcohol would be required to make a high potency remedy. For example, consider the production of a 10,000 potency; to make such a potency would require approximately 50 liters of alcohol—an expensive proposition! It is unlikely that water or alcohol will make any difference in the actual process of potentization, as various mixtures of both have been used successfully in the past. It would therefore be preferable to use double-distilled water for all of the intermediary potencies. Any potency, however, which is to be stored for use as a remedy should be preserved in pure alcohol. Water is not a good medium for preservation because microorganisms tend to grow over time and might interfere with the action of the remedy. Alcohol, on the other hand, is an excellent preservative and can be relied upon to maintain potencies indefinitely.

In any case, careful attention should be paid to the standards of purity of all materials being used in this delicate process. As can be imagined, even small amounts of contamination can be exaggerated tremendously during potentization. Therefore, the environment in which potentizing machines are used must be as free as possible from dust, chemical odors, sunlight, etc. The vials used should be of high chemical standards. The water and alcohol used must be at least of high chemical standards and then at least double-distilled into even greater purity. The tops of the vials used, from experience, should be made of cork (or at least lined by cork), and the cork should be of high quality. The milk sugar used in trituration and for administration of remedies should be of high quality, and the mortar and pestle used should be heated to high temperatures before preparing each remedy.

Nomenclature

Terminology used in naming potencies on different scales has evolved over time. Unfortunately, it has led to conventions which are slightly confusing to the beginner.

The *decimal* scale is based on dilution of 1/10. The first 1× potency is a 1/10 dilution. The second dilution (1/10 × 1/10 = 1/100) is called a 2× potency. The eighth decimal dilution 1/10 × 1/10 × 1/10 × 1/10 × 1/10 × 1/10 × 1/10 × 1/10 × = 1/100,000,000) is called the 8× potency. Thus the potency on the decimal scale is equivalent to the number of zeros in the denominator of the final dilution.

The *centesimal* scale is the most commonly used in homeopathy. It is based upon serial dilutions of 1/100. Each centesimal potency, therefore, is equivalent *in dilution* to two decimal potencies. A 30c potency is the same as a 60×, considering only the amount of dilution.

Finally, some homeopaths are using potencies based on serial dilutions of 1/50,000 at each level. These are called *50-millesimal* potencies, but common parlance refers to them simply as *millesimals.* This unusual dilution factor was suggested by Hahnemann late in his life, based upon his preliminary experimentations with different degrees of dilution and succussion. For example, a 1m potency is a dilution of 1/50,000, and a 3m potency represents a dilution of 1/125,000,000,000,000 (1/50,000 × 1/50,000 × 1/50,000).

It is very important to understand that both *dilution* and *succussion* are important in producing a given level of clinically effective potency. For each potency level, a standard number of succussions are performed, as well as dilution according to the particular scale being used. Figure 14 shows a table in which potencies of equivalent number on different scales are compared as to their dilutions and the number of succussions received (assuming a standard 100 succussions at each level).

Since both factors are involved in potentization, it is incorrect to equate potencies according to mere succussion or mere dilution. For example, if we compare a 30c and a 30×, both have the same number of succussions (3000), but they have different dilutions ($1/10^{30}$ for the 30×, and $1/10^{60}$ for the 30c); so the 30c is a higher potency by some amount. Conversely, if we compare two remedies of equal dilution, a 30c to a 60×, we see that the 60× is

of a higher potency because it has had 6000 succussions, compared to the 3000 given to the 30c.

Occasionally, the problem arises in clinical practice as to which potency on one scale corresponds in effectiveness to a potency on another scale. For example, suppose a patient has had a certain effect from a 30c, the same remedy is still indicated, but the homeopath wants to change to a millesimal scale. Which potency corresponds on the millesimal scale to the 30c? If a 9m is given, is it a higher potency because the dilution is greater? Or is it a lower potency because the succussions are much less? This question cannot be answered with precision as yet, but it should be a good subject for investigation in the future. Someday, it may be possible to devise a formula which would provide this comparison, but as yet there are too many unknown factors. For example, do succussion and dilution have equal importance, or is one more important than another? Or is one factor more important at lower potencies, and the other at higher potencies? Does a given number of succussions have a constant effect at different dilutions, or does the effect vary for different dilutions? Are there different effects below Avogadro's number, especially when appreciable amounts of the original substance are still present, or is the ratio of original substance to solvent irrelevant? Anyway, for the present, the only way of resolving this issue is by the clinical experience of the most astute observers in homeopathy; at the present time, the issue is still unresolved.

By convention and habit arising out of experience, there are certain potencies which are used routinely in homeopathy: 2X, 6X, 12X, 30c, 200c, 1000c, 10,000, 50,000c. For ease in communication, the "c" is deleted when describing potencies from 30c and above; thus we refer to a "200th potency" rather than saying "20-Oc." Also, because some of the higher numbers are unwieldy, we adopt Roman numeral designations: 1000 becomes a 1M, a 10,000 potency becomes a 10M, a 50,000 potency is a 50M, 100,000 is called CM, and so on. The "M" is designated as a capital letter in this book to differentiate it from "m," which means "50-millesimal" scale of potentization. There do exist potencies called *ultra-high* potencies which go to MM (1,000,000c), 50MM (50,000,000c), CMM (100,000,000c), MMM (1,000,000,000c), etc. In addition, a homeopath may rarely give an unusual potency for certain reasons—such as a 17X, a 500c, etc.

As mentioned in Chapter 7, Avogadro's number corresponds in dilution to a 24X, which is a 12c or between a 5m and 6m. This

means that beyond this point, there is no longer any molecule of the original substance remaining. Thus potencies of 10M or MMM are astronomically far beyond any possibility of maintaining any chemical effect of the original substance. The fact that the energy, or vibration rate, of the original substance is transferred to the solvent molecules was discussed in Chapter 7.

Centesimal			*Decimal*			*50-Millesimal*		
POTENCY	DILUTION	No. SUCCUSSIONS	POTENCY	DILUTION	No. SUCCUSSIONS	POTENCY	DILUTION	No. SUCCUSSIONS
1c	$\frac{1}{10^2}$	100	1x	$\frac{1}{10}$	100	1m	$\frac{1}{50\times10^4}$	100
2c	$\frac{1}{10^4}$	200	2x	$\frac{1}{10^2}$	200	2m	$\frac{1}{2.5\times10^9}$	200
3c	$\frac{1}{10^6}$	300	3x	$\frac{1}{10^3}$	300	3m	$\frac{1}{1.25\times10^{14}}$	300
6c	$\frac{1}{10^{12}}$	600	6x	$\frac{1}{10^6}$	600	6m	$\frac{1}{1.5\times10^{28}}$	600
30c	$\frac{1}{10^{60}}$	3000	30x	$\frac{1}{10^{30}}$	3000	30m	$\frac{1}{9\times10^{136}}$	3000
200c	$\frac{1}{10^{400}}$	20,000	200x	$\frac{1}{10^{200}}$	20,000	200m	$\frac{1}{9\times10^{919}}$	20,000

Figure 14: A comparison of dilutions and succussions at each potency level on each scale. This table can be studied in two ways. One can compare a certain number of succussions (say, 20,000) with the extreme differences in dilution found on different scales. Another way is to consider which potencies have approximately similar amounts of dilution yet have received quite different numbers of succussions.

Hahnemann, being a chemist, was well aware of Avogadro's number, but it is indicative of the openness of his mind and his emphasis or empirical observation that he went ahead anyway and used potencies that exceeded Avogadro's number—and he found them to be increasingly effective with fewer adverse effects than lower potencies. At this point, however, many of Hahnemann's followers could not follow him. Their belief was strongly grounded in the materialistic philosophy emerging at the time, so they found it inconceivable that medicines could act beyond the material level. This caused a major split in homeopathic circles, which eventually became called the split between *low potency* and *high potency* prescribers. (Generally, low potencies are remedies below Avogadro's number, and high potencies are considered those above it).

Describing this split as being based upon the potencies used by homeopaths does not adequately express the true nature of the

schism. Those prescribers who broke from the leadership of Hahnemann tended to reject not only his use of high potencies, but many of his other principles as well. They favored mixing many remedies together, giving a variety of potencies at once, repeating remedies frequently throughout days or weeks, prescribing upon the organ affected or the diagnostic label, giving remedies to produce "drainage" of the system, etc. In short, the low potency prescribers by and large utilized homeopathic remedies in an almost purely allopathic manner. These practices are still in vogue in many areas of the world today and are seriously disrupting the possibilities of cure of many thousands of cases.

It is also misleading to describe classical Hahnemannian prescribers as high potency prescribers. A homeopath conforming to the strict laws of homeopathy is likely to use *any* potency, depending upon the individual needs of the patient. It is true that they most commonly rely upon potencies above Avogadro's number, but there are always circumstances when even a 6× may be used. Thus the true schism has little to do with the potencies used but rather with the entire philosophy and method of prescribing.

Annotated Bibliography for Chapter 11

1. Hahnemann's description of Causticum:

Lime, in the state of marble, owes it insolubility in water and its mildness to an acid of the lowest order which is combined with it; when head to red heat the marble allows this acid to escape as a gas. During this process the marble, as burned lime, has received (besides the latent heat) another substance *into its composition, which substance, unknown to chemistry, gives to it its caustic property as well as its solubility in the water, whereby we obtain lime-water. This substance, though itself not an acid, gives to it its caustic virtue, and by adding a fluid acid (which will endure fire), which then combines with the lime by its closer affinity, the watery caustic (Hydras Caustici?) is separated by distillation.*

Take a piece of freshly burned lime of about two pounds, dip this piece into a vessel of distilled water for about one minute, then lay it in a dry dish, in which it will soon turn into powder with the development of much heat and is peculiar odor, called lime-vapor. Of this fine powder take two ounces and mix with it in a (warmed) porcelain triturating bowl a solution of two ounces of bisulphate of potash, which has been heated to red heat and melted, cooled again and then pulverized and dissolved in two ounces of boiling hot water. This thickish mixture is put into a small glass retort; to which the helm is attached with wet bladder; into the tube of the helm is inserted the receiver half submerged in water; the retort is warmed by the gradual approach of a charcoal fire below and all the fluid is then

POTENCIES

By Debra LeRoy B.Sc. DIHom FBIH

Being a unique feature of Homoeopathic medicine, potencies differentiate Homeopathy from Allopathic medicine, Herbal medicine and the Bach remedies. In the physical sense, potencies are energised dilutions (attenuations) of the mother tinctures of homoeopathic remedies. Hahnemann believed that material atoms were not necessary to acquire a specific, invisible medicinal force. Instead, Hahnemann relied on the invisible energy of the substance, which is released and liberated by progressive potenisation methods.

All homoeopathic remedies have potency numbers. The potency numbers, which follow the name of the homoeopathic remedies are indicative of the number of dilutions and succussions from the original mother tincture. Succussions are potenisation steps. Potenisation is carried out in two steps. Serial (sequential) dilution of the mother tincture with a mixture of alcohol and water, is followed by the second step, commonly referred to as succussion. Succussion involves vigorous shaking (preferably 100 times!) with violent impact. Dilutions may be performed in two series. The decimal series is based on dilutions of 1:10 and the centesimal series is based on dilutions of 1:100. The decimal series of dilutions is denoted by the letter "X" and the centesimal series is denoted by the letter "C". Therefore, the equation used to calculate the decimal potencies is written as Nx=10n, whilst the equation for centesimal dilution is Nc=102n. However, for preparing potencies higher than 200C, the Korsakov method is often employed. The Korsakovian method is simpler and quicker. Korsakov's method involves using the same container for each serial dilution, while Hahnemann's method uses a different container for each serial dilution. The Korsakov method was adopted favourably by physicians and pharmacists. Jahr stated, in 1841, "for dilutions one does not wish to keep, the obtained dilution can be emptied out and the same flask can be filled with one hundred drops and shaken one hundred times in order to achieve the next dilution". In view of the amount of time required for the Hahnemann method, it is doubtful that any potencies claimed to have been produced higher than 1M are genuine. Although Hahnemann's method is scientifically accurate, the Korsakovian method lends itself well to computerisation and automation, rendering it the preferred choice for very high potencies.

The word potency means "power or strength". In the procedure of potenisation, succussion energises the dilution and this is stored as potential energy. The common belief among Homoeopaths is that the energy is released from the infintesimally small, catalytic homoeopathic dose as kinetic energy. This kinetic energy is able to activate or stimulate the body's own natural defence system mechanism to effect a cure. It is sometimes assumed that the higher the potency, thus, the higher the dilution, the

greater the healing power. Although often the case, this is not impervious. Consideration must be given to this power in terms of the correct choice of potency, for each individual case. Experience and skilful choice of potency on the practitioner's part is required to optimise the healing energy that is constrained in the potency.

In accordance with the Similimum, and given the selection of the correct remedy in the case, potencies are able to modify or enhance the therapeutic activity of the remedy, therefore rendering it a powerful tool at the hands of a skilful practitioner. Conversely, while potency is of great importance in homoeopathic prescribing, the choice of the correct remedy, in accordance with the Similimum is of principle, essential importance. Theoretically, if the correct remedy is chosen to treat an illness, it may lead to some improvement in the illness, no matter what potency is prescribed. However, an inappropriate or incorrect remedy, (one that is poorly matched with the patient's symptom picture) will be of little or no merit, whatever potency is prescribed.

There are specific prime potencies which are universally prescribed. Potencies may be categorised as low, medium, high or very high potencies. Low potencies consist of 3X, 6X, 12X and 6C. The medium range is 24X, 30X and 30C. High potencies include 200C and 1M (or 1,000C). Very high potencies are 10M, 50M and CM (dilution 1 x 10-200,000). The prime potencies, and those most often used are: 6X, 6C, 30C, 200C and 1M, in homoeopathic practice. However, different countries favour different potencies. For example, in France, potencies above 30C are not permitted by law, so practitioners use 4C, 5C, 7C, 9C and 30C most often. Gemmotherapy and Lithotherapy preparations are prescribed in potencies of 2X and 8X only, respectively. Gemmotherapy and Lithotherapy, being relatively new to the field, were developed by the French School, and all clinical work to date has been confined to these potencies only. Organotherapy (Sacrcodes) are prescribed in only three levels: 4C, (low), 6C or 7C, (medium), or 30C (high). The Homoeopathic Pharmacopedia of the United States, the 8th edition (Part ii) which is published in 1994, states the recommended lowest potencies for each specific remedy for retail (over-the-counter) sales and prescriptions. With this in mind, it is imperative to remember that remedies derived from highly toxic substances (Rhus Toxicodendron or Atropa Belladonna) must not be prescribed in very low potencies; low potencies referring to large material doses. Allergens are usually prescribed prophylactically, in a potency of 30C. Frequency of dosage varies greatly, according to individual circumstances, but typically, it may be daily or weekly. Hayfever, or allergic rhinitis, would be treated during the high pollen season only. Typically, Mixed Grass Pollen in a potency of 30C or Euphrasia in a potency of 30C would be utilised. Bowel Nosodes are prescribed in a single dose of 30C potency only. However, a repeat dose may be given after three months.

All advice regarding the choice of potencies is generalised. Each case is highly individual and every practitioner must draw upon their own experience to decide the appropriate potency to prescribe. Hahnemann stated, in "The Organon of Medicine", paragraph 278, "Only pure experiment, the meticulous observation of the sensitivity of each patient, and sound experience can determine this in each individual case".

Boericke's Homoeopathic Materia Medica gives the practitioner some general guidance on the choice of potency at the end of each entry listed. These notations are very general. In some cases, later clinical experience has superseded the recommended potencies listed. These recommendations should not be taken too literally.

Most Homoeopathic pharmacies have, what are commonly termed "pre-potencies" or "stock potencies". This enables the pharmacy to prepare supplies of prime potencies quickly, ensuring their freshness. Stock potencies have numbers one less than the prime potencies. Thus, potencies of 5X, 5C, 199C and 999C are stocked. In this arrangement, only one potenisation step is required to produce the prime potencies as and when they are needed. This is necessary for convenience, as it is clearly not practical to go back to the mother tincture every time a potency of 1M is required.

Hahnemann favoured potencies of 6X, 12X, 24X, 3C and up to 30C. In the latter part of his career, he even experimented with potencies up to 50C. Hahnemann also introduced LM potencies in the Organon, paragraphs 246 - 283. In the potencies, the dilution ratio was increased from 1:10 or 1:100 to 1:50,000 and the dilution succussed at least 100 times. The potencies of LM1, LM2 and LM3 etcetera acquire tremendous support from some homoeopaths.

There has been much research into discovering why Hahnemann chose potencies of 3, 6, 12, 24 and 30 in the first place. T.M. Cook observed (Brit. Hom. J. 1982) that the potencies so favoured by Hahnemann are sub-units or multiples of the numbers 6 and 12. As Hahnemann was influenced by the duodecimal system of counting in his everyday life, which also uses sub-units of twelve, such as 12 inches to the foot and 12 hours to the clock face, this theory is not without merit. However, it remains a mystery as to why commonly prescribed higher potencies, such as 200C, 1M and CM are based on the metric or decimal system in units of 10. Cook has hypothesized that, since these higher potencies were not introduced until the late 19th and early 20th Century, this would be valid. Cook correctly argued that the metric system, based on units of 10, had been generally adopted by medicine and science by that time. It is therefore logical to assume that Kent et al would specify these metric numbers when introducing these higher potencies into homoeopathic practice. The remaining question is that, if Hahnemann did, in fact, use the old duodecimal system in prescribing, why did he specify metric (or decimal) dilutions in the preparation of homoeopathic medicines, such as 1:10 or 1:100. Since Hahnemann regarded the practice of Homoeopathy as an art, hence the title, "The Organon of the Art of Healing", perhaps he chose potency numbers in everyday use as an art form (duodecimal), and chose the universal, scientific metric system for the scientific preparation of potencies.

Generally, acute diseases are treated with low prescribed dosages at a high frequency of dosage. Typically, a remedy may be prescribed hourly or three times a day. For instance, Aconite 6X each hour for four hours may be prescribed at the onset of a cold. Chronic diseases, being viewed as more deep seated than acute diseases, and probably of an inherited nature, are usually treated with high potency remedies. As well, the

frequency of dosage is lower. Therefore, potencies of 200X, 200C or 1M, may be prescribed and administered once a day, every other day, once a week or once a month. However, these high potencies may be preceded, in certain circumstances, by a lower prescribed potency. If the right remedy is chosen in the first place, but the potency is too high, then there is no where to go.

Today, most practitioners follow either the example of Dr. Richard Hughes of England, or Dr. James Tyler Kent, of the United States. Dr. Hughes believed in a scientific approach to prescribing at the physical level, based on the totality of symptoms, and, typically utilised potencies of 3X, 6X or 6C. On the contrary, devotees of Dr. Kent prescribed high potencies on a constitutional basis for a wide range of conditions. This approach concentrated on the mental, emotional and psychological level. Even the spiritual level was treated with very high potencies of 1M, 10M, 50M or even CM in a single dose. In this way, the same patient may receive the same remedy, according to his or her constitution, for many different illnesses. Other practitioners take a broader view and encompass both approaches, depending upon the individual nature of the case. There is immense clinical evidence of successful treatment with both high and low potencies over the last 150 years. Therefore, it is entirely up to the practitioner to decide on the potency, only after scrutinising all the available information in each individual case.

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HOMEOPATHY

A Frontier In Medical Science

Experimental Studies
and Theoretical Foundations

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cation, but obviously they could not be used as such in human experimentation. It was thus that their effects were tested in healthy subjects (provings) and in patients (curative homeopathy) at low and very low doses, administered repeatedly until symptoms appeared (or disappeared, as the case may be).

In the course of these initial trials, Hahnemann himself claimed to have observed the following phenomena:

a) If a patient needed a remedy, i.e. if there was a match within the framework of the law of similars, he or she tended to be very sensitive to the remedy itself. Thus, the doses necessary and sufficient to obtain a positive reaction, were much lower than those needed to cause symptoms in healthy subjects or to cure a sick person who did not present a perfect symptom match.

b) On the strength of this observation, he began to dilute the remedies in order to find curative doses that did not produce unwanted side effects. Experience led him to note an increase in the curative potency on reducing the dose, i.e. on increasing the dilutions.

c) The early dilution procedures also included the process of succussion or trituration of the raw materials (according to whether they were liquid or solid) for a wholly practical reason, consisting in the homogeneousness of the diluted product; only later was it observed that this procedure was necessary to increase the effect of the dilutions. For this reason the progressively increasing dilutions were also called *potencies* and the dilution and succussion process was called *potentization* or *dynamization*.

In practice, the raw materials are extracted by solubilization in alcohol containing various percentages of water, or, if insoluble, they are initially pulverized and triturated with lactose and then diluted in a water-alcohol solution. The initial solutions, containing the maximum concentrations of active ingredients, are called *mother tinctures* (MT). Successive dilutions are then operated, followed by vigorous shaking.

The preparation techniques for the various types of remedies used today are codified in detail in the various pharmacopoeias, the most important of which are the French and German ones, though there is a tendency to find a consensus, at least at the level of the European Union.

The most commonly used dilutions/potencies are: 1:9 (labelled "D," "DH," "X, "or "x"), when 1 part of the most concentrated solution is diluted in 9 parts of solvent; or 1:99 (labelled "C," "CH," or "c"), when 1 part of the most concentrated solution is diluted with 99 parts of solvent. There are also dilutions labelled "LM," based on 1:50,000 serial dilutions, and even *Korsakovian* dilutions (labelled "K"), based on dilutions produced

by emptying the recipient containing the most concentrated solution, leaving a few droplets in the bottom, and filling it with solvent (obviously, this latter method is harder to standardize, despite being simple to perform). Lastly, mechanized continuous-flow procedures are also used today.

It is well known that often—though not as a rule—extremely high dilutions are used, with the result that theoretically there is no longer so much as a single molecule of the original substance remaining. This constitutes one of the cornerstones of homeopathy, and at the same time is perhaps the main problem which research is called upon to confirm and possibly explain.

Another very important point has to do with the so-called *dynamization*. In the procedure for the preparation of homeopathic drugs, the rule is that, after each dilution, the resulting solution be subjected to vigorous shaking. Classic standard practice prescribes 100 downward shakes, but other succussion procedures have been developed, including automated techniques.

Lastly, there are also preparations in granule or globule form, consisting in small spheres of sucrose or lactose impregnated with the Hahnemann dilution, from which they take their name. For example, *Arnica montana* (mountain daisy) 9c granules are granules which have been impregnated with the 9c dilution of *Arnica montana*.

Further details on the preparation techniques for homeopathic remedies can be found in other reviews [Vithoulkas, 1980; Del Giudice and Del Giudice, 1984; Brigo and Masciello, 1988; Winston, 1989; Majerus, 1991].

2.3 *Hahnemann's* Organon

The history of homeopathy [Lodispoto, 1984; Gibson and Gibson, 1987; Haehl, 1989; Majerus, 1991; Ullman, 1991a; Ullman 1991b] begins with the ideas and discoveries of its founder C.F.S. Hahnemann. It was he who first coined the term homeopathy from the Greek *homoios* ("similar") and *pathos* ("suffering"), referring to the law of similars which is its basis. Hahnemann's first real insight into the law of similars came in 1789, when he was translating a book by W. Cullen, one of the most eminent physicians of the era. At a certain point, Cullen attributed the efficacy of Peruvian bark (cinchona) in the treatment of malaria to its bitter and astringent properties. Hahnemann, who was also an expert chemist and keen experimenter, was not happy with this explanation, since he was well aware that there were many other more bitter and astringent substances than Peruvian bark, which, however, were devoid of efficacy in antimalarial treatment. He therefore began to experiment on himself by taking repeated doses of Peruvian bark extract until he reached a stage where he started to manifest fever, chills, and other symptoms similar to those of malaria.

X. RELATED PROCEEDINGS APPENDIX

NONE.